UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS Judge Patti B. Saris Magistrate Judge Marianne B. Bowler
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	

UNITED STATES' OPPOSITION TO ROXANE'S MOTION FOR LEAVE TO DEPOSE CAROLYN HELTON AND ROBIN KREUSH STONE

More than seven months after the close of fact discovery, Roxane seeks leave to take additional depositions in the hope of finding evidence that will bolster its motion for summary judgment. Roxane's motion should be denied because the discovery it seeks is irrelevant. Furthermore, (1) Rule 56(f) is not available to a party seeking to support its *own* motion for summary judgment; (2) Roxane's attempt to establish as an "undisputed material fact" that the Durable Medical Equipment Regional Carriers ("DMERCs") "misclassified" Roxane's NovaPlus ipratropium bromide product as a brand is legally and factually unfounded; and (3) Roxane could have obtained the additional discovery it now seeks during the discovery period.

Carolyn Helton and Robin Stone are employed by two of the four DMERCs responsible for calculating Medicare reimbursement for ipratropium bromide during the relevant time period. Both Ms. Helton and Ms. Stone were deposed during the discovery period, and each offered a declaration in conjunction with the United States' summary judgment papers filed on July 24, 2009. Roxane now seeks leave to re-depose Ms. Helton and Ms. Stone regarding two topics

addressed in their declarations, but which Roxane did not explore during the witnesses' depositions: the DMERCs' classification of NovaPlus ipratropium bromide as a "brand" product; and the DMERCs' inclusion (or exclusion) of Zenith Goldline products in their quarterly pricing arrays.

Roxane fails to provide a legal basis for its request, instead simply characterizing the United States' claims as "frivolous," and putting forth the red herrings that the United States purportedly changed damages theories at the "eleventh hour," and submitted declarations which improperly contradict prior sworn testimony. These assertions are meritless. Roxane has failed to establish any reason why it could not have deposed Ms. Helton or Ms. Stone on these topics during fact discovery, particularly since DMERC pricing arrays produced to Roxane included information showing that NovaPlus ipratropium bromide was classified as a brand, and that Zenith Goldline products were excluded from some pricing arrays. Finally, the classification of NovaPlus ipratropium bromide is only relevant to *Roxane's* motion for summary judgment, and Rule 56(f) only applies to parties *opposing* summary judgment. Roxane's Motion should be denied.

I. BACKGROUND

In its Complaint filed on February 9, 2007, the United States identified the HCPCS codes applicable to ipratropium bromide (J7645, K0518, and J7644). The Complaint also put Roxane on notice that from 1999 through 2003, Medicare reimbursement was based on the lower of 95% of the median of published generic AWPs or the AWP of the least expensive brand name drug. Complaint, ¶¶ 42, 55 (citing 42 C.F.R. § 405.517). The DMERC pricing arrays for the ipratropium bromide HCPCS codes were produced to Roxane in January and March 2008. Exh.

A. Those arrays show that Roxane's NovaPlus ipratropium bromide products were included among the products considered by the DMERCs in setting reimbursement for ipratropium bromide, and that three of the four DMERCs treated NovaPlus ipratropium bromide as a "brand." The United States has consistently taken the position that its damages analysis would likely include a traditional "but for" calculation of damages. Exh. B, at p. 10-11. In instances where the DMERCs classified NovaPlus ipratropium bromide as a brand, such an approach naturally suggests that damages are calculated by replacing the AWPs for NovaPlus ipratropium bromide with truthful AWPs, and quantifying the difference in reimbursement. The United States never said that its damages analysis would disregard the DMERCs' determination that NovaPlus ipratropium bromide was a brand.

The United States also has consistently taken the position that all NDCs for a particular drug or included within a particular HCPCS code were within the scope of the Complaint, irrespective of whether the particular NDC was identified in the Complaint. In a June 16, 2008 letter, for example, the United States informed Roxane that if Roxane "marketed any of the Subject Drugs under different NDC numbers than those listed in the Complaint, any such alternative other NDC numbers would, in the Plaintiffs' view, be within the scope of the Complaint." Exh. C, at p. 3. In a September 25, 2008 letter, the United States specifically informed Roxane of its view that the NovaPlus ipratropium bromide NDCs were within the scope of the Complaint and that the United States intended to "move for leave to amend its complaint to formally include the NovaPlus ipratropium bromide products." Exh. D. The United States filed its motion to amend on October 20, 2008, and the Court granted leave to amend on November 25, 2008.

Ms. Stone was deposed in this case on February 28 and 29, 2008. Ms. Helton was deposed on March 13, 2008. Neither witness was asked specifically about the classification of NovaPlus ipratropium bromide, nor the decision to include or exclude the Zenith Goldline products from the DMERC pricing arrays. Roxane was on notice of the United States' position that the NovaPlus ipratropium bromide products were within the scope of the Complaint by September 25, 2008, at the latest. Nonetheless, Roxane never sought to re-depose Ms. Stone or Ms. Helton during the three remaining months of fact discovery. Roxane did, however, depose a representative of a third DMERC (Cheryl Eiler) for several days in August and September 2008.

The declarations offered by Ms. Helton and Ms. Stone are entirely consistent with their prior deposition testimony, as well as with the testimony of Ms. Eiler. With regard to the classification of NovaPlus ipratropium bromide, Ms. Helton and Ms. Stone state in their declarations that they classified the product in accord with CMS instructions and based on whether the product's name differed from the chemical name. The prior deposition testimony from the DMERC witnesses establishes that the DMERCs consulted the printed copies of the Red Book in determining whether products were brands or generics, but that the DMERCs stopped using the printed Red Books in or around 1999, prior to NovaPlus ipratropium bromide ever appearing in a DMERC pricing array. Exh. E (8/27/2008 Eiler Dep. at p. 292-93); Exh. F (3/13/2008 Helton Dep. at p 147). With regard to the Zenith Goldline products, Ms. Stone states in her declaration that this product was excluded from the pricing arrays because it was "preservative free." The prior deposition testimony establishes that preservative free products were often excluded from pricing arrays due to their higher cost. Exh. E (8/27/2008 Eiler Dep. at p. 289-91); Exh. G (8/26/2008 Eiler Dep. at p. 147-48).

II. ARGUMENT

A. Rule 56(f) Only Applies to Parties Seeking Discovery to Oppose Summary Judgment

As an initial matter, Fed. R. Civ. P. 56(f) is not available to Roxane as a basis for the relief it seeks. The Rule provides that if "a party *opposing*" a motion for summary judgment shows that "it cannot present facts essential to justify its *opposition*" then the court may, among other things, order a continuance to enable further depositions to be taken. Fed. R. Civ. P. 56(f) (emphasis supplied); *see also, e.g.*, *Rivera-Torres v. Rev-Hernandez*, 502 F.3d 7, 10 (1st Cir. 2007) ("bedrock" principles under Rule 56(f) include that it is available "to mount an *opposition*" only where the party shows, *inter alia*, how the discovery sought "will suffice to *defeat* the pending summary judgment motion") (emphasis supplied). Here, as Roxane concedes, *Roxane* raised the issue of NovaPlus ipratropium bromide's classification as an argument for summary judgment in its favor. Roxane's Mem. in Supp. of Summary Judgment (M.D. # 6200; Sub. # 257), at 12-25. The United States addressed the issue only in opposition to Roxane's Motion.[1]

B. Roxane's Assertion That the DMERCs "Misclassified" NovaPlus Ipratropium Bromide Is Wrong

Roxane's motion begins with the mistaken premise that the DMERCs' classification of NovaPlus ipratropium bromide as a brand was an error. As detailed at pages 25-31 of the United States' Consolidated Memorandum of Law (M.D.# 6291, Sub.# 298-3), the classification of NovaPlus ipratropium bromide was in accord with CMS' published rules, which define a brand product as a product that is "marketed under a labeled name that is other than the generic

[1] *See* United States' Consolidated Memorandum of Law (M.D.# 6291, Sub.# 298-3), p. 7 n. 7.

chemical name of the drug or biological." 63 Fed. Reg. 58,814, 58,849 (Nov. 2, 1998). CMS specifically considered and rejected a definition of "brand" that was limited to the product of the innovator company:

> Our definition of "brand" is any product that is marketed under a name other than the generic chemical name of the drug. If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand. We do not limit the definition of "brand" to the innovator company product or any product manufactured under a direct license from the innovator.

Id. The evidence plainly establishes that NovaPlus® is a proprietary name, and Roxane's promotion of NovaPlus ipratropium bromide consistently identified the product as part of the NovaPlus® brand. Acting pursuant to CMS' published guidance, three of the four DMERCs *correctly* treated NovaPlus ipratropium bromide as a brand. Since the classification was appropriate, further discovery about how or why the DMERCs classified NovaPlus® products as they did, is simply irrelevant.

C. Roxane Could Have Deposed Ms. Helton and Ms. Stone During the Discovery Period on The Topics at Issue

Roxane argues that it was somehow misled by the United States about the basis on which damages would be calculated, suggesting it did not have enough information to ask the DMERC witnesses the salient questions during the discovery period (or, indeed, at any point prior to the United States' filing of its summary judgment papers on July 24, 2009). Roxane also misleadingly claims that the United States' submission of the Helton and Stone declarations was an "eleventh-hour" effort to interject new and contradictory evidence. Roxane Memorandum in Support of Motion to Depose Carolyn Helton and Robin Stone, at p. 1, 4-5. These arguments fail for two main reasons. First, Roxane's counsel had every reason to understand that the United

States was likely to employ a traditional "but for" damages analysis and quantify the amount that Medicare would have reimbursed had Roxane not reported inflated AWPs. For periods when NovaPlus ipratropium bromide was classified as a brand, such a damages theory logically entails replacing the NovaPlus® AWPs (which three DMERCs placed in the brand side of the pricing arrays) with truthful AWPs, and then quantifying the difference in reimbursement.[2] Second, documents produced to Roxane long before the close of discovery showed how the DMERCs classified NovaPlus ipratropium bromide, and there was nothing misleading about the testimony or representations by the United States.

Roxane protests that it was surprised when the United States' expert report of Mark G. Duggan, Ph.D., calculated damages using a "but for" scenario that accepts the DMERCs' treatment of NovaPlus® as a brand.[3] This assertion is disingenuous, as Dr. Duggan simply undertakes a traditional calculation based on the difference between what Medicare actually paid on claims reimbursed under the pertinent HCPCS codes, and what Medicare would have paid had Roxane reported truthful AWPs for both its generic ipratropium bromide products and its NovaPlus® products. As noted above, the United States consistently took the position that its damages analysis would likely include a traditional "but for" quantification of damages. Since Roxane knew that NovaPlus ipratropium bromide was classified as a brand since March 2008 (at the latest), and that the United States intended to amend its complaint to formally include the NovaPlus® NDCs since September 25, 2008 (at the latest), Roxane can hardly claim to have been

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[2] This damages model is well established under the False Claims Act. *See BMY Combat Systems v. United States*, 44 Fed. Cl. 141, 147 (Ct. Cl. 1999); *United States v. Killough*, 848 F.2d 1523, 1532 (11th Cir. 1988); *United States v. Woodbury*, 359 F.2d 370, 379 (9th Cir. 1966).

[3] Dr. Duggan also calculates damages based on a comparison that ignores the impact of the false NovaPlus ipratropium bromide prices.

surprised that the United States' damages calculations include a model reflecting the DMERCs' classification of NovaPlus ipratropium bromide as a brand.

Nor has Roxane shown that the government misled Roxane into believing it would treat NovaPlus ipratropium bromide as a generic. Roxane's argument ignores that the DMERC arrays (produced to Roxane in January and March 2008) themselves treated NovaPlus® products as brands. Roxane misleadingly claims that one of the DMERC witnesses, Cheryl Eiler, testified that she classified drugs based on the typeface listed in the printed Red Book. Ms. Eiler, however, never testified that she used the printed version of the Red Book during the period relevant to the NovaPlus® products – in fact, her testimony demonstrates that she stopped using the printed Red Book in 1999, prior to NovaPlus ipratropium bromide appearing in any DMERC pricing array. Exh. E, at p. 292-93. Furthermore, Ms. Eiler offered no testimony regarding how the other DMERCs classified drugs. Thus, Roxane is simply wrong in suggesting that there is any inconsistency between the prior deposition testimony of the DMERC witnesses, and the Helton and Stone declarations.[4]

Finally, Roxane makes much out of the fact that in its motion to amend, the United States stated its belief that the DMERC witnesses would not need to be re-deposed. This is a non-issue for at least two reasons. First, Roxane was not bound by the United States' argument; *nothing* prevented Roxane from seeking to depose additional DMERC witnesses, or to re-depose Ms.

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[4] Nor should the Court be distracted by Roxane's suggestion that a *question by counsel* at a deposition acted as "explicit confirmation" of the government's "position" and the "pre-existing evidentiary record" that Novaplus was a generic. Roxane Memorandum in Support of Motion to Depose Carolyn Helton and Robin Stone at pp. 4-5. It is axiomatic that questions of counsel to a witness are not evidence, *see Hawthorne v. Michelin Tire Corp.*, 100 F.3d 962, 1996 WL 640481 (9th Cir. 1996); *United States v. Cudlitz*, 73 F.3d 992, 1002-1003 (1st Cir. 1996). Roxane also cannot credibly claim that such a question was a binding representation as to the United States' potential arguments on the issue.

Helton or Ms. Stone, during the discovery period. More important, however, such further discovery was unnecessary then, and remains so. Roxane can make no showing of prejudice if denied the opportunity to question Ms. Helton and Ms. Stone on why they classified NovaPlus ipratropium bromide as a brand, since the classification was *correct* according to a rule published in the Federal Register, and such testimony is therefore immaterial. As discussed in detail at pages 26 - 31 of the United States' Consolidated Memorandum of Law (M.D.# 6291, Sub.# 298-3), Roxane was on notice that products marketed under proprietary names were treated as brands, and Roxane's NovaPlus ipratropium bromide was properly treated as such by three DMERCs.[5]

III. CONCLUSION

Accordingly, Roxane's Motion should be denied.

DATED: August 6, 2009

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[5] Roxane makes no attempt to argue that it could not have deposed Helton and Stone regarding the Zenith Goldline products during the discovery period. The relevant arrays showing that some DMERCs excluded the Zenith Goldline products were produced to Roxane in January and March 2008.

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

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Dated: August 6, 2009